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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,061	02/18/2004	Adam T. Zemla	11-11160	5751

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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09/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/782,061

Applicant(s)

ZEMLA, ADAM T.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/21/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Claims

1. Amendment filed 06/21/2007 is acknowledged.

Claims pending are 1-13. Claims 8 remains withdrawn from consideration as being drawn to a non-elected species. Claims 1-7, 9-13 are under consideration.

Drawings

2. The drawings were received on 06/21/2007. These drawings are not acceptable. Figures 2,3,6 remain to be illegible. Reference to publication of applicants having legible color drawings is not sufficient. If the only way of presenting the drawings in question in legible way is color drawings, applicant is invited to submit the color drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 1-7, 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons.

Claim 1: It is not clear whether the three steps of "comparing" recited in the claim are conducted independently or sequentially.

A. Claim 7: It is not clear whether the three steps of "comparing" recited in the claim are conducted independently or sequentially. Claim 1 is amended to recite that all steps are conducted independently but the same issue remains for claim 7.

B. Claims 1,7: The step of using LGA_S analysis is vague and indefinite: specification, in the section defining the scoring function LGA_S (p. 17), fails to identify variables k , X , $S(F)$, $S(LCS)$, w^* used in calculation of the scoring function; thus, the function is undefined.

Response to arguments

Applicant refers to publication of A. Zemla providing the details of the calculations. Such reference is not sufficient. Calculation of the scoring function LGA_S is subject matter essential for conducting method as claimed. Incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d

569, 179 U.S.P.Q. 157 (C.C.P.A. 1973); *In re Hawkins*, 486 F.2d 579, 179 U.S.P.Q. 163 (C.C.P.A. 1973); and *In re Hawkins*, 486 F.2d 577, 179 U.S.P.Q. 167 (C.C.P.A. 1973).

C. Similarly, the term “apply the transform” in claims 3,9 is vague and indefinite. The term “transform” is not defined by the claim. The specification, also, does not provide a standard for ascertaining the requisite composition, and one of ordinary skills in the art would not be reasonably appraised of the scope of the invention.

Response to arguments

Applicant merely states that the term “apply the transform” is sufficient for an artisan, without providing any arguments to support the statement. This is not deemed persuasive.

D. Claim 1: As addressed in the preceding Office action, it is not clear what constitutes “the calculated alignment”. Examiner agrees that amending claim 1 to recite “using LGA_S analysis to provide a calculated alignment” removes the lack antecedent basis issue. However, the meaning of the term “calculated alignment” is not clear: while the claim states that LGA_S analysis is used “to provide a calculated alignment”, specification teaches that this analysis is used to merely “evaluate” calculated alignment (paragraph [0038]). In turn, while specification teaches what constitutes the quality of the calculated alignment (“distances between the corresponding residues, LCS data and GDT data”; see paragraph [0046]), it does not teach how the “calculated alignment” itself is being calculated. Note that both Longest Continuous Segments (LCS) and Global Distance Test (GDT) analysis are used to compare the first and the second molecule rather than to calculate alignment (see paragraph [0038], for example).

G (new). Claim 1 is amended to recite that each of the method steps of claim 1 is conducted independently. It is not clear how the LGA_S analysis can be conducted independently of the preceding LGS and GDT steps if it accounts for the results of these steps – see Fig. 1 and formula for LGA on p. 17.

Claim Rejections - 35 USC § 112, first paragraph (New Matter).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 introduces new matter as it addresses LGA_S analysis as performed independently of other method steps. The disclosure in specification is limited to LGA_S analysis performed following the preceding method steps and accounting for their results. See Fig. 1 and formula for LGA on p. 17.

Claim Rejections - 35 U.S.C. § 101(utility)

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The following is a quotation of the 35 U.S.C. § 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

5. The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. The following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. § 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

See also the MPEP at §§ 2107 - 2107.02.

Claims 1-7, 9-13 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The rejection is maintained for the reason of record and further in view of the following.

Applicant argues that the method as claimed provides information about protein folding. There is nothing in the claims, however, providing a nexus between providing an uncertain amount of information about 3D similarities between proteins and their ability to properly fold or misfold. Nor there is any guidance provided by applicant regarding relevant disclosure of such utility in the specification.

Applicant then reiterates that the claimed invention allows comparison of 3D similarities between two proteins. As addressed in the rejection, as a result of computational determination, regions having 3D similarity in two protein molecules are identified. However, such result lacks substantial utility as subsequent research is needed to identify the utility of finding such 3D similarities. Thus, Zu-Kang (reference submitted by applicant) teaches that studies based on superimposition of 3D structures are "bound to be misleading" (end of Abstract).

Applicant further cites post-filing date art. The applicant cannot rebut the rejection by relying on a utility that would not have been readily apparent at the time the application was filed. See, e.g., *In re Wright*, 999 F.2d 1557, 1562-63, 27 USPQ2d 1510, 1514 (Fed. Cir. 1993). See Utility Guidelines, p. 1095, bottom of the left column.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-7, 9-13 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention.

Response to arguments

See response to utility rejection above. In addition, same as in the case of utility requirement, the referenced art is not considered because the references are of post-filing date and enablement sufficiency of a specification is determined as of its filing date. See MPEP 2164.05(a)

Further, as addressed in (non-addressed by applicant) part of the rejection, due to ambiguity of the term "to transform", and variables used in determining the LGA_S score (see rejections under 35 U.S.C. 112, second paragraph), the specification is not enabling as one skilled in the art would not know how to make, and thus how to use, the invention as claimed.

Claim Rejections - 35 U.S.C. § 101 (non-statutory invention)

7. Claim 1-7, 9-13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The rejection is maintained for the reasons of record.

As addressed in the rejection, for a claim to be “useful,” the claim must produce a result that is specific, substantial, and credible. As discussed in the utility rejection above, the invention does not satisfy the criteria of utility requirements as not being substantial. Therefore, the claims are rejected as non-statutory for failing to comply with 35 USC 101, i.e., not providing a useful, concrete and tangible result.

In addition the claims are broader than the disclosure. With respect to claim 1, the term “complete”, as in “complete information” is now removed from the claim) about “calculated alignment” obtained from a single step of LGA_S analysis (the latter being performed independently from other method steps) is removed such that it does not require a practical application, then the claim must be rejected. With respect to claims 7+, the claims encompass embodiments of the computational method wherein either all three steps of comparing are done independently one from another, or these steps can be performed on unrelated parts of the protein structures. Such embodiments of the method as claimed are not viewed as directed to any practical application.

Applicant reiterates the same recitation of post-filing date art references as in the traversal of utility and enablement rejections. This is not considered persuasive for the reasons set forth above.

Claim Rejections - 35 USC § 102.

8. Claims 1,2,4-7,10-13 remain rejected under 35 U.S.C. 102(b) as anticipated by Lackner et al (reference submitted by applicant).

The instant claims are drawn to method of finding 3D similarities in protein structures of a first molecule and a second molecule. The method comprises providing preselected information regarding the first molecule and the second molecule, comparing the first molecule and the second molecule using Longest Continuous Segments (LCS) analysis, comparing the first molecule and the second molecule using Global Distance Test (GDT) analysis, and comparing the first molecule and the second molecule using Local Global Alignment Scoring function (LGA_S) analysis.

The Longest Continuous Segments (LCS) analysis determines percent of residues (longest continuous segment) that can fit under cutoff of root mean square (RMSD) cutoff.

The Global Distance Test (GDT) analysis determines percent of residues (largest set, not necessary continuous) that can fit under the cutoff of distance between residues which might be either contiguous or non-contiguous.

The LGA_S scoring function combines the results of LCS and GDT.

Because multiple terms remain not defined in the specification (see rejections under 35 U.S.C. 112, second paragraph, above), Examiner remains unable to conduct full search of prior art. Thus, the following art rejection addresses the general idea of the invention, namely fulfilling not only RMSD restrictions, but also including distance restrictions in evaluating 3D similarities between structure of two protein molecules. As

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stated by applicant, "the scope of the invention is not intended to be limited to the particular forms disclosed and the invention covers all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the claims" (p. 9, paragraph [0015]).

Lackner describes method of finding 3D similarities between protein structures using ProSup algorithm which determines segments that can fit under RMSD cutoff (i.e., the approach addressed in the instant application as Longest Continuous Segments (LCS) analysis). In the course of this analysis Lackner also uses distance limitations which introduce distance cutoff for alignment construction. See Table 1, and discussion of parameters d_c and d_e on p. 747. Although the instant method addresses distance as being between not necessarily contiguous segments of residue pairs, it also reads on using distance cutoff for contiguous residues as well. For the latter embodiment, the referenced method reads on the instant method as claimed.

With regard to claims 4,10, Lackner's method is used regardless to sequence similarity:

With regard to claims 5,11,13,intended use limitation does not impart patentability of claims.

Response to arguments

In traversal of the rejection applicant merely recited, step by step, all of the steps of claim 7, and asserted that the reference does not teach at least one of these steps. Applicant failed to address teaching of the reference described in the rejection. Instead, in the traversal of the rejection, applicant merely recited, step by step, all of the steps of claim 7, and asserted that the reference does not teach at least one of these steps (note that the response addresses the recited steps in the alternative "OR", so it is not clear

which of the steps, in applicant's opinion is not taught by the reference). The argument is not deemed to be persuasive; the rejection is maintained.

Conclusion.

9. No claims are allowed

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb